

DEPARTMENT OF THE NAVY

BUREAU OF MEDICINE AND SURGERY 2300 E STREET NW WASHINGTON DC 20372-5300 Canc frp: Oct 99

IN REPLY REFER TO

BUMEDNOTE 3900

BUMED-26

1 Oct 98

BUMED NOTICE 3900

From: Chief, Bureau of Medicine and Surgery

To: Naval Medical Research and Development Laboratories

Subj: PROTECTION OF HUMAN SUBJECT VOLUNTEERS FROM RESEARCH RISKS

Ref:

- (a) SECNAVINST 5212.5C
- (b) SECNAVINST 5211.5D
- (c) CNO ltr Ser 093/2U239066 of 10 Mar 92
- (d) OPRR Report "Policy on Informing those Tested About HIV Serostatus" of 10 Jun 88
- (e) OPNAVINST 5300.8A
- (f) NAVMEDRSCHDEVCOMINST 3900.2
- 1. <u>Purpose</u>. To provide policy for the protection of human subjects from research risks per references (a) through (f).
- 2. <u>Scope</u>. This instruction applies to all human subject volunteers involved in medical research conducted, supported, or otherwise subject to regulation by Bureau of Medicine and Surgery (MED-26) activities.
- 3. Policy. Reference (f) is to remain in effect until further notice. This instruction applies to all studies, regardless of funding source, conducted at, by, or in collaboration with any BUMED (MED-26) activity. Studies include preliminary activities (e.g., calibration of equipment and collection of pilot data) that precede the main data collection effort. Responsibility for the protection of human subjects from research risks is a command responsibility involving all hands. In all work governed by this instruction, the welfare of human subject volunteers is considered preeminent and, along with full compliance with applicable regulations and BUMED policy, takes precedence over specific research programs.
- 4. <u>Cancellation Contingency</u>. Canceled upon incorporation into BUMED Instruction 3900.6A.

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